

# **EXHIBIT I**

## Andrew N. Faes

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**From:** Andrew N. Faes  
**Sent:** Friday, May 10, 2013 7:45 PM  
**To:** 'Ben Watson'; PCombs@tcspllc.com; Maha Kabbash  
**Cc:** Tom P. Cartmell; Bryan Aylstock; 'Renee Baggett'; Zonies, Joe; Greg Bentley; Donna Jacobs; Christy Jones  
**Subject:** RE: Production of documents prior to 30(b)(6) design deposition

Mr. Watson;

I must say I'm a little perplexed by your response. First of all, you indicated back in March that you were attempting to locate copies of the applicable IFU's. Are you telling me that that the attempt is still underway, is complete but proved fruitless, or has been abandoned altogether? Further, I understand that Medscand was listed as the manufacturer of the TVT device at the time of its 510(k) clearance on 01-28-1998, but it was Ethicon who owned and submitted the 510(k) and was marketing and distributing the device during the time period we are asking about: 01-28-1998 through 01-16-2001. Further, you state that Medscand Medical AB is an entity "unrelated to Ethicon." It was my understanding that Ethicon ultimately assumed ownership of the device, and would have received documentation regarding the device from Medscand as part of the manufacturing transfer. Is my understating regarding this incorrect?

Ultimately, I want to be 100% clear on what you seem to be telling me: that neither Ethicon or Johnson & Johnson has any of the final in-use versions for the TVT device during the 01-28-1998 through 01-16-2001 time period, and cannot verify which versions of the IFU were in use during that time period despite distributing and marketing the device, and submitting the 510(k) application- and that your production regarding these documents is complete. Is that statement correct?

### Andrew N. Faes

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